

Art Unit: 1636

DETAILED ACTION

Claims 1-9 are currently pending. Claims 4-5 have been withdrawn. Claims 1-3 and 6-9 are currently under consideration.

Election/Restrictions

Applicant's elected Group I (claims 1-3) in the reply filed on July 29, 2009 **without** traverse.

Claims 4-5 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Inventions, there being no allowable generic or linking claim.

Withdrawn rejections

Any rejection presented in the Office Action mailed December 23, 2010 and not reiterated below is hereby withdrawn.

New Rejections Necessitated by Amendments

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 recites the method of claim 1 further comprising contacting the hydrophilic

Art Unit: 1636

regions with a first type of sample and a second type of sample. However, claim 1 recites contacting with a sample. It is unclear if applicants intend for both contacting steps to be performed (e.g.: contacted with a first sample as in claim 1 and then further contacted with another sample as in claim 9) or if applicants intend for the contacting step to be performed only once, but with different samples. As the claim now reads, it indicates that the hydrophilic regions are being contacted with a sample twice.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 9 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a **new matter** rejection.

Claim 9 recites the method of claim 1 further comprising contacting the hydrophilic regions with a first type of sample and a second type of sample. Applicants point to the specification p 9, which recites different sample solutions. However, the specification as filed does not provide support for the limitation that the hydrophilic regions are contacted multiple times. If applicant disagrees, applicant should specifically point out where support for this limitation is in the specification.

Art Unit: 1636

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 6-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thurnheer et al. (Automated fluorescent in situ hybridization for the specific detection and quantification of oral streptococci in dental plaque, 2001, Journal of Microbiological Methods, Vol 44, pp 39-47), McCormick et al. (US Patent 7498176, filed September 29, 2003, and earlier priority date), and, if necessary, Grant Boekel Laboratory Equipment (dated 06/2001 on p 16, 16

Art Unit: 1636

pages, accessed from

<http://www.wolflabs.co.uk/Catalogue/Grant%20Boeckel%20%20Brochure.pdf> on May 26, 2011).

Regarding present **claims 1 and 6**, Thurnheer et al. teach a hybridization method comprising immobilizing a plurality of different cell types (i.e.: “probes”) in separate wells of a microscope slide, adding 20 • 1 of hybridization solution comprising probe (i.e.: sample biopolymer) to each well and incubating the slides in a plastic tube equipped with a piece of paper towel and 2 mL of hybridization buffer to equilibrate humidity (i.e.: a vessel comprising a solution having the same vapor pressure as the solution comprising the sample biopolymer, since it is the same solution, wherein the vessel solution is not in contact with the solution comprising the sample biopolymer as the solution comprising sample is in the wells, and wherein the volume of solution in the closed vessel is at least five times the quantity of the solution comprising the sample biopolymer; see entire document, particularly p 40, col 2, Table 1).

Regarding present **claims 7-8**, Thurnheer et al. teach DNA probes to hybridize to the RNA in the cells (see Table 1).

Regarding present **claim 9**, Thurnheer et al. teach adding different probes to the different wells (see Table 1, Figure 1).

While Thurnheer et al. teach a hybridization method, Thurnheer et al. do not teach forming a slide with hydrophobic regions and hydrophilic regions.

Regarding present **claim 1**, McCormick et al. teach forming a microarray comprising a plurality of different genes/probes (i.e.: DNA or RNA, as recited in instant claim 8) in a plurality of hydrophilic subarrays surrounded by a hydrophobic barrier, which inhibits fluid

Art Unit: 1636

communication between each subarray, to prevent cross contamination of multiple samples hybridized in parallel to each subarray (i.e.: wherein no probe is hybridized to the hydrophobic region, wherein the sample biopolymer is not in contact with the hydrophobic regions; see entire document, particularly col 1, lns 50+, col 2, lns 25-49, col 3, lns 30-35, and 65+, col 5, lns 9-11, Figures 3-4). Thurnheer et al. also teach forming the hydrophobic regions around the plurality of hydrophilic regions (see col 3, lns 30-35, 56+, col 4, lns 1-5) and that the array can be used to analyze a large number of samples, which also reads on solutions comprising different sample biopolymers of instant **claim 9**.

While Thurnheer et al. and McCormick et al. teach a hybridization method utilizing a slide with hydrophobic and hydrophilic areas and hybridization in a container comprising a solution with the same vapor pressure, Thurnheer et al. do not specifically teach closing the chamber (although it is noted that this would be standard practice).

However, Grant Boekel Laboratory Equipment teach a hybridization chamber wherein the "sealed and clamped chamber maintains humidity so the probe doesn't dry out" and that "humidity is maintained merely by adding a small amount of hybridization solution to the tray" (see p 6), which reads on the closing step of instant **claim 1**.

Therefore it would have been obvious to one of skill in the art at the time of the invention to utilize a slide with hydrophobic and hydrophilic areas as taught by McCormick et al. and a closed hybridization chamber as taught by Grant Boekel Laboratory Equipment in the hybridization method taught by Thurnheer et al.

One would have been motivated to do so because McCormick et al. teach the benefits of such a slide, such as the ability to analyze multiple sample simultaneously and allowing the use

Art Unit: 1636

of all potential synthesis sites (see col 1, lns 51+, col 2, lns 45-48) and Grant Boekel Laboratory Equipment teach that their system is a simple and efficient system for the incubation of slides (see p 6).

One would have had a reasonable expectation for success because all of the cited references teach various methods and equipment for conduction hybridization on slides.

Therefore the teachings of Thurnheer et al., McCormick et al., and Grant Boekel Laboratory Equipment renders the present invention *prima facie* obvious.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Art Unit: 1636

Future Communications

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHANNON JANSSEN whose telephone number is (571)270-1303. The examiner can normally be reached on Monday-Friday 10:00AM-7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Shannon L Janssen

SLJ

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1636